

Class 2 Recall; Biomet 3i T3 Dental Implant,

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?start_search=1&event_id=65005

Biomet 3i recently initiated two recalls of their T3 implants (Z-1960-2013, Z-1961-2013). The reason for the recall is that a small number of outer implant boxes may be mislabeled. The inner tray, containing the implant, is labeled correctly. This condition, if present and not recognized could potentially result in the dental implant not being able to be placed into the osteotomy or seated to the desired depth if placement is attempted.

The implants included in the recall are:

Parallel Walled 6mm (D) x 10mm (L),

Lot number 2012111613 Exp 2017/12

Catalog #: BOPS6510

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=117652>

Non-Platform Switched Parallel Walled Implant 5mm(D) x 13mm (L)

Lot number: 2012101530 Exp 2017/12

Catalog #: BNSS513

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=120466>

Biomet 3i issued an "Urgent Medical Device Recall" notification letters to their customers dated May 10, 2013. The notification described the issue and provided recommendations actions regarding affected product. Customers with questions may contact 1 800-342-5454. The affected products are listed below: